

## **REMARKS**

Reconsideration and allowance of this application and the amended claims therein are respectfully requested. Upon entry of the foregoing amendment, claims 3, 22-24, and 39-73 have been canceled. Claims 1, 2, 4-21, and 25-38 are pending.

Claims 1 and 20 are amended herein. Support for the amendment to claim 1 is found in paragraphs [0016] and [0017] of the specification as filed. Support for the amendment to claim 20 is found in paragraphs [0017], [0083], and [0088] of the specification as filed.

### **1. Interview Summary**

Applicants thank the Examiner for the courtesies extended during a telephonic interview conducted on January 17, 2006. The interview included participants Dr. Sumesh Kaushal, Dr. Mark Roberts, Ms. Corey Crafton, and Mr. Duane Stewart. During the interview, the parties discussed the outstanding Official Action. Amendment of the claims was discussed. Conservation of promoter regions in bacteria was discussed. Submission of a declaration directed to utility was considered. This declaration will be submitted after the filing of this paper.

### **2. Rejections**

#### **A. 35 U.S.C. § 101**

Claims 1, 2, 4-21, and 25-38 stand rejected under 35 U.S.C. § 101 for alleged lack of either a specific asserted utility or a well-established utility. Applicants respectfully submit that this rejection should be withdrawn. All of Applicants' prior arguments directed to the Office Action's failure to establish a *prima facie* case of lack of utility are repeated as if fully restated herein. In particular, the Applicants respectfully submit that the Office has too quickly dismissed

the valuable insight provided by the  $\beta$ -galactosidase activity discussed in the specification. To one skilled in the art, this assay is a clear demonstration of utility.

Furthermore, Applicants repeat that the sequence homology, as shown in Table 1A on page 23 of the specification, coupled with the conserved promoter sequences as shown in Table 2 and included in claim 20, is a clear indicator that could be used by one skilled in the art to judge the utility of the invention. One skilled in the art of bacterial regulation would note the presence of the TACAAT sequence at position 334 of the claimed nucleotide (the -10 conserved region) and the presence of the TTGCCA sequence at position 224 of the claimed nucleotide (the -35 region). These sequences, when conserved, are plain indicators of bacterial regulator activity. This alone should be enough to demonstrate utility to one skilled in the art.

In addition to the amendments and remarks made herein, Applicants will file a supplemental response shortly after the filing of this paper. That response will include a supporting declaration, as discussed during the telephonic interview of January 17, 2006.

#### **B. 35 U.S.C. § 112**

Claims 1, 2, 4-21, and 25-38 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged failure to show a person skilled in the art how to make and use the invention. The Office Action states that the rejection is based on the alleged lack of "either a specific asserted utility or a well established utility for the reasons set forth [in the rejection based on 35 U.S.C. § 101]. . . ."

This rejection is based on the 35 U.S.C. § 101 rejection appearing in this Office Action. As set forth above, that rejection should be withdrawn. Because the rejection under § 101 fails, this rejection must necessarily fail as well for all claims that remain pending. Withdrawal of the rejection and allowance of the pending claims is respectfully requested.

### **3. Conclusion**

All of the stated grounds of rejection have been properly accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all of the outstanding rejections, and then allow all of the pending claims as amended. If the Examiner believes, for any reason, that personal communication will expedite allowance of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,



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